No. 01-188

(22)

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In The
Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, Commissioner, Maine Department of Human Services, and G. STEVEN ROWE, Attorney General of Maine,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

BRIEF FOR RESPONDENTS

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QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. 1396 *et seq.*, prohibits a state from using its prior authorization powers under that statute to compel drug manufacturers to provide rebates for drugs sold to uninsured Maine residents?

2. Whether the Maine Rx statute, 22 Me.Rev.Stat. Ann. § 1281 *et seq.*, which seeks rebate payments in connection with in-state retail sales of prescription drugs to uninsured Maine residents, violates the dormant Commerce Clause because wholesale transactions in those drugs occur outside of Maine?

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CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

In addition to those set forth in Petitioner's brief, the following provision of the Constitution is involved in this matter:

> Article I, Section 8, Clause 1 of the Constitution provides, in pertinent part, that "The Congress shall have Power . . . to pay the debts and provide for the common Defence and general Welfare of the United States."

STATEMENT OF THE CASE

Maine Rx is an effort to preserve and protect the health of Maine residents by lowering the cost of medications to individuals who benefit from neither private insurance nor other public plans. Through this program, Maine seeks to use Medicaid's prior authorization process to encourage pharmaceutical manufacturers to provide rebates on medicines purchased by those individuals. The drugs of those manufacturers that do not agree would be subject to prior authorization in the Medicaid program to the extent permitted by law. Nothing in the language, structure or goals of the Medicaid statute forbids such use of prior authorization.

The Pharmaceutical Research and Manufacturers of America (PhRMA) makes a facial challenge to this statute, arguing that it is both preempted and in contravention of the Commerce Clause. Maine Rx does not burden Medicaid, and, to the extent relevant, does advance its objectives. Maine Rx, moreover, does not discriminate between

in-state and out-of-state competitors and does not regulate out-of-state transactions.

The Solicitor General agrees that Maine Rx does not violate the Commerce Clause, and generally agrees that the structure and purpose of Maine Rx does not contravene Medicaid. The government's primary objection is that Maine has sought to help too many uninsured residents, some of whom, in its view, are not sufficiently needy. The inclusion of this group in the program, however, has not been shown to burden Medicaid.

I. STATUTORY FRAMEWORK

A. Medicaid

1. Medicaid was created by Congress in 1965 pursuant to its spending power under Article I, section 8, clause 1 of the Constitution. The program is one of "cooperative federalism," whereby the federal government provides money to the States to assist them in providing "necessary medical services" to their most needy residents. 42 U.S.C. 1396.

In order to participate, a State must have its Medicaid "State plan" approved by the Centers for Medicare and Medicaid Services (CMS), on behalf of the Secretary of the Department of Health and Human Services (the Secretary), and, once approved, the State is eligible for federal reimbursement for portions of state expenditures on medical assistance under the State plan. 42 U.S.C. 1396a, 1396d(b). One of the forms of "medical assistance" that can be made available through Medicaid is prescription medication. 42 U.S.C. 1396d(a)(12). Drugs have become a major benefit provided by Medicaid. By 1988, for instance,

pharmaceuticals constituted the third largest category of medical assistance offered through Medicaid, eclipsing the amount spent to compensate physicians. *Medicaid Prescription Drug Pricing: Hearing on S.2605 and S.3029 Before the Subcomm. on Health for Families and the Uninsured of the Senate Comm. on Finance*, 101st Cong., 2d Sess. 2 (1990) ("*Medicaid Prescription Drug Pricing*") (statement of Sen. Riegle).

2. By 1990, the escalating cost of prescription drugs was seriously straining the resources of State Medicaid programs. See *Medicaid Prescription Drug Pricing, supra* at 3 (statement of Sen. Pryor) (noting a 152 percent increase in prescription drug prices over the previous decade and the resulting impact on State Medicaid programs). Manufacturers were charging Medicaid programs a much higher price for prescription drugs than they were charging their other large purchasers. H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990); see also *Medicaid Prescription Drug Pricing, supra* at 3. (statement of Sen. Pryor) ("In essence, the drug manufacturers are holding the States and the Federal Government hostage to their price increases.").

Realizing that traditional market forces had failed to ensure Medicaid programs the price concessions typically demanded by large customers, in 1990 Congress prohibited the States from using federal funds to purchase any prescription drugs unless the manufacturer paid an acceptable "rebate." 42 U.S.C. 1396r-8, *et seq.*, enacted as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), Pub. L. No. 101-508, § 4401, 104 Stat. 1388-143. This "rebate" provision generally requires that federal funds only be applied towards a net purchase price that is at least as low as the "best price for which a manufacturer

sells a prescription drug to any public or private purchaser." 42 U.S.C. 1396r-8(c); U.S. Br. 4-5. The Medicaid statute, as amended, sets the minimum rebate amount a state must receive before federal funds will be available. On behalf of all of the states, the Secretary negotiates agreements with manufacturers that provide this minimum rebate. Individual states may negotiate more generous agreements providing for rebate payments exceeding the minimum. 42 U.S.C. 1396r-8(a)(1).[1]

3. The use of "prior authorization" as a tool to save money and to negotiate rebates has always been the prerogative of the states under Medicaid. 136 Cong. Rec. 30, 515 (1990) (noting that States engage in prior authorization without federal or regulatory constraints and that they are free to negotiate discounts with manufacturers). Medicaid will cover the costs of any drug prescribed to a Medicaid beneficiary, provided that the manufacturer has agreed to pay a rebate. When a drug is subjected to prior authorization, however, the State Medicaid agency must approve a doctor's prescription of the drug in order for there to be Medicaid reimbursement. J.A. 288-291.

In 1990, at the same time that it conditioned the release of federal money on receipt by the States of at least the minimum rebate amount, Congress affirmed and ratified the States' broad and historic power to impose prior authorization. Thus, the 1990 amendment to Medicaid provides that "[a] State may subject to prior

[1] The agreement reached must be approved by the Secretary. 42 U.S.C. 1396r-8(a)(1).

authorization *any* covered outpatient drug."[2] 42 U.S.C. 1396r-8(d)(1)(A) (emphasis added). The States could impose prior authorization to achieve "efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990); U.S. Br. at 14-15. Cost-saving is undeniably a goal in administering Medicaid, and prior authorization is a tool to achieve it.

Congress deemed it best that the State Medicaid agencies – as the governmental authorities most sensitive to the needs of Medicaid recipients and physicians who treat them – hold the power to impose prior authorization. Congress made that decision fully aware of allegations that prior authorization pushes doctors toward prescribing less effective medications. *Medicaid Prescription Drug Pricing, supra* at 7-8. The only significant limitation Congress placed on prior authorization was to address the concern that some states were not responding to physicians' prior authorization requests in a timely fashion. Congress thus required that states respond to prior authorization requests within 24 hours and that in emergencies they provide a 72-hour supply notwithstanding the lack of authorization. 42 U.S.C. 1396r-8(d)(5). Three years later Congress added the concept of a formulary (a list of favored drugs) as a fiscal tool, but was careful to leave prior authorization untouched. 42 U.S.C.

[2] Medicaid permits the States to impose a variety of limitations on access to drugs. 42 U.S.C. 1396r-8(d). PhRMA argues (Br. 4-5) that prior authorization is merely the means of achieving these other limitations. But the structure of the statute clearly establishes prior authorization as a separate and distinct power, limited only by the patient protection provisions of 42 U.S.C. 1396r-8(d)(5) and the overarching requirement that Medicaid patients receive all medically necessary prescription drugs. 42 U.S.C. 1396.

1396r-8(d)(4) ("[a] prior authorization program . . . is not a formulary. . . . ").

As the Solicitor General explains, following the grant of the petition for *certiorari* the Secretary confirmed that prior authorization can be used as a tool in negotiating with drug manufacturers to benefit *non*-Medicaid citizens. In a letter sent to the nation's State Medicaid Directors on September 18, 2002, the Secretary conveyed his understanding that Medicaid permits the threat of prior authorization to be used as leverage to negotiate not only for supplemental Medicaid rebates but also for discounts, rebates, and other prescription drug benefits for persons *not* eligible for Medicaid. U.S. Br. 48a-49a.

B. Maine Rx

1. There is no real dispute that people without Medicaid or private insurance covering pharmaceutical expenses pay much more to fill their prescriptions than any other purchasers. Department of Health and Human Services, *Report to the President, Prescription Drug Coverage, Spending, Utilization, and Prices,* April 2000, p. 96; table 3-1, p. 98, http://aspe.hhs.gov/health/reports/drug study/ ("*Report to the President*"). This price discrimination persists because, *inter alia,* there is no purchasing agent to negotiate on behalf of the uninsured. As prices for the uninsured continue to rise, many prescriptions for vital medicines go unfilled.[3]

[3] In 2000, an estimated 22.2% of all Maine residents lacked insurance for prescription drugs. Alan Sager, *Cutting Prescription Drug Spending By Paying Federal Supply Schedule Prices*, Boston University School of Health 1 (Aug. 2000). In 1996, the average Maine senior paid

(Continued on following page)

Maine Rx ameliorates this price discrimination by providing a price discount to the uninsured. Those with prescription drug coverage will not avail themselves of this benefit because the small co-payments typically required by their insurance plans are far less than the after-discount price available to Maine Rx beneficiaries. Thus, enrollment in the program will be self-limiting, as Maine's legislature intended. See 22 Me. Rev. Stat. Ann. § 2681(1) (Maine Rx is not intended to "discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans.") It would be economically irrational for a person with prescription drug coverage to use Maine Rx, but if any patient mistakenly attempts to do so, the Department of Human Services (DHS) has proposed regulations which will not allow it. J.A. 317.

cash for 48.1 percent of their prescription drug expenditures. Amanda McCloskey, *Cost Overdose: Growth in Drug Spending for the Elderly*, Families USA Foundation, 10 (July 2000). In 1998, the average retail price charged in Maine for the ten drugs most commonly used by the elderly was 86 percent higher than the price paid by the manufacturers' most favored customers. Minority Staff Report, *Prescription Drug Pricing in the 1st Congressional District of Maine: Drug Companies Profit at the Expense of Older Americans*, Committee on Government Reform and Oversight, U.S. House of Representatives, prepared for Rep. Thomas H. Allen, ii (Oct. 9, 1998) ("*Prescription Drug Pricing in the 1st Congressional District of Maine*"). Faced with the highest drug prices in the market, some uninsured must choose between buying food and medicine. Others skip doses, split pills or do not fill their prescriptions at all. *Id.* at 4, 16. See also Stephen B. Soumerai, et al., *Inadequate Prescription-Drug Coverage for Medicare Enrollees – A Call to Action*, 340 New Eng. J. Med. 723 (1999). The authorities cited above appear in the record accompanying Defendant's Memorandum of Law in Opposition to Plaintiff's Motion for Preliminary Injunction (Def. Opp. Mot. Prelim. Inj.).

Maine Rx achieves price discounts for the uninsured by empowering DHS to act as a pharmaceutical benefits manager (PBM) to negotiate for "manufacturer rebates and pharmacy discounts" on their behalf. 22 Me. Rev. Stat. Ann. § 2681; Pet. App. 86. The PBM model on which Maine Rx is patterned dominates the private sector health care system. Private PBMs are purchasing agents retained by employers, benefit plans, and insurers to negotiate discounts with manufacturers and pharmacies on their behalf. *Report to the President, supra* at 102-05; see also William H. von Oehsen, III, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, Public Health Institute (2001) 5-6, available at http://www.phpc-rx.org/PHI.Pharm.pdf. PBMs can wield market power because they are able to influence which drugs are dispensed to the individuals participating in the benefits programs they manage. *Id*; see also Pet. App. 38.

Under Maine Rx DHS will induce manufacturers to participate in the program by wielding its purchasing power – specifically its power to subject to prior authorization requirements the drugs it covers through Medicaid. Maine Rx thus relies on the hope and expectation that manufacturers would rather negotiate discounts for the uninsured than find their drugs placed in a disadvantaged position relative to competing and therapeutically similar drugs produced by companies electing to participate in Maine Rx. 22 Me. Rev. Stat. Ann. § 2681(7); Pet. App. 89-90. As noted previously, the Secretary has specifically approved of this approach to benefit residents not eligible for Medicaid benefits.

2. The mechanics of the Maine Rx program are not complex. The Commissioner of DHS (Commissioner) will negotiate with pharmaceutical manufacturers to obtain discounts for qualified residents. The discounts take the

form of rebates triggered by each sale of a Maine Rx covered drug to a Maine Rx cardholder at a participating Maine Rx pharmacy. Maine Rx does not mandate any particular rebate amount – the Commissioner is simply to use his "best efforts" to leverage the State's market power into the most generous discount manufacturers are willing to provide. The initial *goal* is a rebate equal to or greater than the rebate Maine typically receives when it purchases drugs through its Medicaid program (discussed above), with an ultimate goal of rebates approximating those provided to the federal government. 22 Me. Rev. Stat. Ann. § 2681(4); Pet. App. 88. Once an agreement is negotiated, the discounts made possible by Maine Rx rebates will be deducted by participating pharmacies at the point of purchase. 22 Me. Rev. Stat. Ann. § 2681(5); Pet. App. 88. Participating manufacturers will pay rebates quarterly based upon the volume of their drugs purchased by Maine Rx enrollees. 22 Me. Rev. Stat. Ann. § 2681(3); Pet. App. 87.

Under the Maine Rx statute and the administrative rules drafted to guide DHS in implementing the program, prior authorization will consist of a three-step process. First, Maine's Drug Utilization Review Committee will be presented with a list of drugs manufactured by companies that have declined to participate in the Maine Rx program. J.A. 278, 320. Second, the committee, which is comprised of physicians and pharmacists, will consider, on a drug-by-drug basis, whether or not it is "clinically appropriate" to subject a drug on the list to prior authorization. J.A. 149, 268, 278, 320. For instance, a drug with a unique therapeutic use will not be subjected to prior authorization for that use because it would always be medically necessary. J.A. 149. Finally, for drugs which are subjected to prior

authorization, DHS will approve a request to dispense such a drug upon a showing by the treating physician that the patient needs that drug. J.A. 278, 288-91, 320. DHS employs pharmacists to participate in this process. J.A. 151. The proposed administrative rules reflect the statute's mandate that prior authorization be imposed on the drugs of non-participating manufacturers only "as permitted by law." 22 Me. Rev. Stat. Ann. § 2681(7); Pet. App. 89-90. This three-step prior authorization process fully comports with Maine's obligation under Medicaid to provide a "quality of care" that is "consistent with . . . the best interests of the recipients." 42 U.S.C. 1396a(a)(30) and (19).

II. PROCEEDINGS BELOW

One day prior to Maine Rx's effective date, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a complaint setting forth a facial constitutional challenge based on the Supremacy Clause and the Commerce Clause. On October 26, 2000, the United States District Court for the District of Maine granted PhRMA's motion for a preliminary injunction. The court construed the rebate mechanism as an impermissible price control in violation of the dormant Commerce Clause even though it does not discriminate against interstate commerce. Pet. App. 64-66. The court also held that Maine Rx is preempted by Medicaid because it uses Medicaid prior authorization without advancing the interests of either the Medicaid program or its current beneficiaries. Pet. App. 68.

On May 16, 2001, a unanimous panel of the Court of Appeals for the First Circuit reversed. After finding that PhRMA has prudential standing to raise a preemption

objection to Maine Rx, the court of appeals held that the statute survives the attack on the merits because it does not conflict with the purposes of Medicaid. Pet. App. 8, 13. The circuit court recognized that Maine need not shoulder the burden of demonstrating that Maine Rx affirmatively advances the aims of Medicaid. Pet. App. 13. Nonetheless, the court concluded that even if that were the test, Maine Rx would pass muster because it tends to preserve the fiscal viability of Medicaid by keeping the uninsured healthy and employed so that they will not slip further into poverty and, consequently, Medicaid eligibility. *Id.*

Turning to PhRMA's Commerce Clause challenge, the circuit court rejected the notion that seeking rebates from an out-of-state manufacturer violates the dormant Commerce Clause. The court held that while such a rebate might have an effect on manufacturers' profits, such an effect does not constitute impermissible regulation of out-of-state transactions. Pet. App. 23. Finally, after noting that PhRMA had not alleged that Maine Rx discriminates against interstate commerce, the court held that whatever incidental burden Maine Rx might actually have on interstate commerce was not "'clearly excessive' as compared" to the local health benefits for Maine's uninsured residents. Pet. App. 25-27 (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)).

PhRMA sought a panel rehearing and a rehearing *en banc*. The panel refused to rehear the case, and, because the full court was unable to consider the request for *en banc* review due to the recusal of all but one of the active judges of the court, that motion was also denied. Pet. App. 55-56. Thereafter, upon PhRMA's further motion, the court

granted a stay of its mandate pending *certiorari*. J.A. 31-33.

This Court granted *certiorari* review on June 28, 2002. Consequently, the order of the circuit court granting a stay of its mandate remains in force, as does the October 26, 2000 injunction issued by the district court.

SUMMARY OF THE ARGUMENT

Maine Rx is not preempted by Medicaid and does not violate the Commerce Clause. The judgment of the circuit court should be affirmed.

1. PhRMA fails the zone of interest test required for prudential standing. Federal law does not provide the requisite interest because Medicaid was not enacted to protect the interests of pharmaceutical manufacturers or to regulate that industry, and none of its provisions has that effect. Nor can the requisite interest be derived from the Supremacy Clause, which concerns the relative powers of the state and federal government in our constitutional system and does not, in and of itself, create interests.

2. Medicaid does not preempt the Maine Rx program. Medicaid expressly authorizes the States to impose prior authorization on *any* prescription drug, and Maine has satisfied the few conditions imposed on that authority. There is no implied preemption because Maine Rx does not irreconcilably conflict with the primary purposes of Medicaid. To the extent relevant, Maine Rx advances the goals of Medicaid by preserving the health and productivity of Maine residents who lack insurance. Maine Rx also creates financial benefits for Medicaid by using prior

authorization to reduce the State's purchase of unduly expensive drugs, by limiting the growth of the Medicaid rolls, and by increasing the State's power to negotiate lower prices for prescription drugs.

3. Maine Rx also does not infringe the dormant Commerce Clause. The Act does not discriminate against interstate commerce because it does not give in-state economic actors an advantage over out-of-state competitors. Maine Rx allows the interstate market to function without restraint and is wholly consistent with the principle of a national economic union. It has neither the purpose nor effect of protecting in-state industry. Further, Maine Rx is not an impermissible extraterritorial regulation. It has no effect on prices in other states, directly or indirectly. Regardless of whether Maine Rx rebates affect drug manufacturers' profits, the Act is not a price control and does not regulate out-of-state wholesale transactions. The Solicitor General agrees that Maine Rx does not run afoul of the dormant Commerce Clause. U.S. Pet. Br. at 15-18.

ARGUMENT

I. PhRMA DOES NOT HAVE PRUDENTIAL STANDING TO ASSERT THAT MAINE RX IS PREEMPTED BY MEDICAID.

The circuit court concluded that PhRMA's interests need not fall within the zone of interests protected or regulated by the Medicaid statute, instead finding that PhRMA has prudential standing "grounded in the Supremacy Clause" itself. Pet. App. 7-8. This was error.

Prudential standing is a "judicially self-imposed limit[] on the exercise of federal jurisdiction." *Allen v. Wright*, 468 U.S. 737, 751 (1984). Like the "irreducible constitutional minimum of [Article III] standing," prudential standing is "'founded in concern about the proper – and properly limited – role of the courts in a democratic society.'" *Bennet v. Spear*, 520 U.S. 154, 162 (1997) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) and *Warth v. Seldin*, 422 U.S. 490, 498 (1975)). To satisfy these prudential standing concerns "a plaintiff's grievance must arguably fall within the zone of interests protected or regulated by the statutory provision or constitutional guarantee invoked in the suit." *Id.*; see also *National Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 492 (1998).

Here, the interests PhRMA seeks to advance are two-fold. First, drug manufacturers desire to ensure that Medicaid reimburses for their drugs without requiring prior authorization. Second, drug manufactures would like to avoid paying rebates in connection with purchases by Maine residents not covered by Medicaid or private insurance.

PhRMA lacks prudential standing, however, because neither concern is within the zone of interests protected or regulated by the Supremacy Clause or Medicaid.[4] The

[4] Prudential standing is a live issue in this case because the First Circuit addressed it without accepting PhRMA's argument that Maine had waived the issue by not arguing it in the district court. Pet. Rep. 5. The district court itself noted that Maine was free to raise the issue in proceedings "on the merits after the preliminary injunction stage." J.A. 233.

Supremacy Clause does not provide the requisite zone of interests because it does not, by its own force, protect or regulate any interests. *Chapman v. Houston Welfare Rights Org.*, 441 U.S. 600, 613 (1979). See also *Dennis v. Higgins*, 498 U.S. 439, 450 (1991) and *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103, 107 (1989). The Supremacy Clause merely gives "priority" to interests that are separately protected or regulated by a federal law whenever they come in conflict with state law. PhRMA must look to the allegedly preempting federal statute to find an interest to support standing.

The federal statute, however, also does not supply the requisite interest. First, Medicaid protects the interests of patients, not the interests of pharmaceutical manufacturers in maintaining a particular market share. See *Tap Pharmaceutical v. U.S. Dep't of Health & Human Servs.*, 163 F.3d 199, 208 (4th Cir. 1998) (manufacturer's financial interest in improving the market share of its product does not fall within the zone of interests protected by Medicare). The only relevant mention of drug manufactures in the Medicaid statute is in the rebate provisions, which are intended to ensure that manufacturers do not overcharge Medicaid, as Congress determined they had been doing prior to 1990. See *Pharmaceutical Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 225 (D.C. Cir. 2001) (discussing origins of rebate provision).

Second, Medicaid does not regulate the pharmaceutical industry. The rebate provisions simply establish the price discounts that the federal government demands in its role as a purchaser of prescription drugs. Manufacturers agree to those provisions only to the extent they wish to avail themselves of the Medicaid market. Such provisions are not enforced against them in the same manner

as are, for instance, regulations under the Federal Food, Drug and Cosmetic Act. 21 U.S.C. 355.[5]

PhRMA attempts to supplement its tenuous claim to an "interest" under Medicaid by arguing (Pet. Rep. 6; Br. 23) that the Medicaid rebate provisions should not be judged on their face, but should be understood as part of a "*quid pro quo*" between drug manufacturers and Congress. That *quid pro quo*, the argument goes, gave the drug manufacturers an interest in ensuring that every Medicaid beneficiary has unrestricted access to every drug for which there is a Medicaid rebate agreement. Of course, a statute is not to be interpreted by the subjective understanding of a lobbying interest. More fundamentally, PhRMA's view cannot be squared with the statute. Medicaid has never prohibited the States from imposing limits and conditions on purchases of prescription drugs. In fact, the 1990 amendments specifically ratified the states' authority to control drug use by imposing prior authorization. 42 U.S.C. 1396r-8(d)(1)(A). Congress enacted the rebate provisions to stop drug manufacturers

[5] *St. Thomas-St. John Hotel & Tourism Ass'n v. Virgin Islands*, 218 F.3d 232, 238 (3d Cir. 2000) and *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624 (1973), relied upon by PhRMA (Rep. Br. Opp. 5), do not advance the prudential standing analysis here because both cases involved comprehensive, federal regulatory schemes promulgated pursuant to Congress' powers under the Commerce Clause. Medicaid, enacted pursuant to Congress' spending powers, is not a comprehensive scheme for regulating the pharmaceutical industry.

from overcharging state Medicaid programs, not to endow drug manufacturers with new rights or interests.

Rejection of PhRMA's claim to standing would not create a safe-harbor for Maine Rx because the federal government is uniquely situated to enforce Medicaid's primacy through the power of its purse. "In legislation enacted pursuant to the spending power, the typical remedy for state noncompliance with federally imposed conditions is not a private cause of action for noncompliance but rather action by the Federal Government to terminate funds to the State." *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1, 28 (1981). See 42 U.S.C. 1396c. The two sovereign parties to the Medicaid "contract" are appropriately left to themselves to resolve any conflict that the Secretary perceives between Maine Rx and Medicaid, with judicial review, if any, of the Secretary's final decision on the matter available pursuant to the procedures set forth in 42 U.S.C. 1316(a)(3).

II. MAINE RX IS NOT PREEMPTED BY MEDICAID

A. Maine Rx Does Not Contravene Medicaid's Primary Objective of Providing Medically Necessary Medicine to Medicaid Beneficiaries.

In Part I of its brief, PhRMA argues that the Maine Rx program is preempted not because it contravenes any express Medicaid provision but rather because it so conflicts with the objectives of Medicaid as to be unconstitutional on its face. Pet. Br. at 14-23. A presumption against preemption, particularly implied preemption, applies as "the States are independent sovereigns in our federal

system," and the Court has "long presumed that Congress does not cavalierly pre-empt" state law, "particularly . . . [when] . . . Congress has 'legislated in a field which the States traditionally occupied.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Protection of the health of their residents is undeniably a traditional responsibility of the States. Additionally, the case for inferring an intent on the part of Congress to prohibit or otherwise limit state behavior, and thus the case for preemption, is weakest when the allegedly preempting statute was enacted pursuant to Congress' spending powers under Article I, section 8 of the Consitution.

> [L]egislation enacted pursuant to the spending power is much in the nature of a contract: in return for federal funds, the States agree to comply with federally imposed conditions. The legitimacy of Congress' power to legislate under the spending power thus rests on whether the State voluntarily and knowingly accepts the terms of the 'contract.' There can, of course, be no knowing acceptance if a State is unaware of the conditions or is unable to ascertain what is expected of it. Accordingly, if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously. By insisting that Congress speak with a clear voice, we enable the States to exercise their choice knowingly, cognizant of the consequences of their participation.

Pennhurst State School & Hospital, 451 U.S. at 17 (citations omitted); see also *New York State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405 (1973). Here, Congress did speak clear and in positive terms: "[a] state may subject to prior

authorization any covered outpatient drug." 42 U.S.C. 1396d(1)(A).

The test for implied preemption asks whether the challenged state statute "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).[6] "Any conflict must be 'irreconcilable . . . . The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute.'" *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 110 (Kennedy, J., concurring in part and concurring in the judgment) (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982). And it is not sufficient to show a conflict with some subsidiary provision of Medicaid – PhRMA must show "direct contradiction" with one of Medicaid's "*primary* objectives as conveyed with clarity in the federal legislation." *Gade*, 505 U.S. at 110 (emphasis added). Because "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case," *Medtronic*, 518 U.S. at 485 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)), the Court hews closely to the "explicit statutory language and the structure and purpose of the statute." *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990); see also *Gade*, 505 U.S. at 111 (Kennedy,

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[6] PhRMA agrees that this is the conflict preemption test, and has recast its "question presented" accordingly. *Compare* Br. i ("Whether the federal Medicaid statute . . . *precludes* Maine from limiting Medicaid patients' access to prescription drugs as a means of compelling drug manufacturers to subsidize discounts for non-Medicaid populations") (emphasis added) *with* Pet. i ("Whether the federal Medicaid statute . . . *allows* a state to use [prior authorization] authority under that statute. . . . ") (emphasis added).

J.) (admonishing that "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law."). By pressing a facial attack, PhRMA takes on "the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987); see also *California Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 579-80 (1987).

PhRMA makes no such showing. Although framed in a variety of ways, PhRMA's position distills down to the belief, without the support of any facts in the record, that Maine Rx will harm Medicaid beneficiaries. This belief is founded on the view that Maine Rx will inevitably "burden" doctors and state Medicaid administrators so as to deprive beneficiaries of the medicines they need. With no evidence to substantiate these beliefs, PhRMA's facial challenge fails as a matter of law.

The "burden" of prior authorization, moreover, is explicitly contemplated by Medicaid. It makes no difference whether prior authorization is imposed because a manufacturer refuses to participate in Maine Rx or for some other reason – the "burden" it places on patients and their physicians is the same in either case. PhRMA has identified nothing inherent in the Maine Rx prior authorization process that distinguishes it from prior authorization otherwise available to and utilized by states.

Thus, PhRMA has not and cannot present any evidence that Maine Rx's use of prior authorization will "harm" Medicaid beneficiaries any differently than prior

authorization in general will "harm" them. Maine, as it has pledged, will continue to abide by the time limitations set forth in the Medicaid statute. 42 U.S.C. 1396r-8(d)(5); J.A. 166-67. Maine will continue to provide all medically necessary prescription drugs in satisfaction of Medicaid's fundamental requirements. 42 U.S.C. 1396; J.A. 151, 167.

PhRMA's case, therefore, rests on a general disdain for prior authorization that Congress did not share.[7] Prior authorization, no matter why it may be imposed, does not contravene Medicaid because prior authorization is nothing more than a mechanism for testing whether a particular drug is "medically necessary." As the Court explained in *Beal v. Doe*, 432 U.S. 438, 444-45 (1977), "[a]lthough serious statutory questions might be presented if a state Medicaid plan *excluded necessary* medical treatment from its coverage, it is hardly inconsistent with the objectives of the Act for a State to refuse to fund *unnecessary* – though perhaps desirable – medical services." (emphasis added).

With the advent of multiple therapeutically equivalent medications in recent years, there is often no single

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[7] The pharmaceutical industry's vigorous opposition to prior authorization in general dates back to at least 1990 when it unsuccessfully lobbied against it. *Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 Before the Subcomm. on Health for Families and the Uninsured of the Senate Comm. on Finance*, 101st Cong., 2d Sess. 38, 139 (1990) (statements of Gerald J. Mossinghoff, president of the Pharmaceutical Manufacturers Association) (arguing that prior authorization should not be allowed by the Medicaid statute, and also warning that if Congress adopts the premise of therapeutic equivalence between some drugs it will create a system of "second-class medical care for Medicaid recipients.").

drug that is indispensable for treating a given patient. In the rare case that only one drug will suffice, the State will grant authorization and provide the drug regardless of whether it is manufactured by a company that participates in Maine Rx. Where, however, the health care professionals on Maine's Drug Utilization Review Committee have determined that multiple therapeutically sufficient therapies are available, no one of them is "medically necessary" within the meaning of Medicaid. In that case, it is simply irrelevant to Medicaid's primary purpose whether the doctor's second choice rather than first choice is prescribed. In fact, where the first choice is more expensive than the second choice, the *failure* to require prior authorizations would result in unnecessary expenditures of state and federal Medicaid funds.[8]

PhRMA goes on to theorize that Maine Rx will inevitably harm Medicaid patients by burdening doctors and state Medicaid administrators, and their ability to provide medically necessary medicine. Pet. Br. at 15-16. Both

[8] For instance, PhRMA-member company SmithKline Beecham, pointing to a study of the U.S. Centers for Disease Control and Prevention (CDC), asserts that prior authorization of Augmentin (its "flagship antibiotic") will harm children suffering from ear infections. J.A. 112, 104. But practicing Maine pediatrician Dr. H. Burtt Richardson prescribes "Augmentin as a *second line* drug after another drug, usually high dose amoxicillin, has failed to adequately treat an ear infection." J.A. 154 (emphasis added). Dr. Richardson's clinical judgment is based not only on the fact that "Augmentin is 3 to 6 times as expensive as amoxicillin," but also that "amoxicillin is effective in treating ear infections 80-85% of the time." J.A. 154. SmithKline's own 1999 annual report notes that the CDC "recommended *Augmentin* as a *second line* of defence when amoxycillin has failed." SmithKline Beecham plc, *1999 Annual Report* 22 (2000), also available at http://www.gsk.com/financial/financialreports.htm, Def. Opp. Mot. Prelim. Inj.; see note 5, supra. (second emphasis added).

doctors and Medicaid employees already handle prior authorization requests as a matter of routine, both for Medicaid and for third party payors. J.A. 149. If Maine Rx results in a marginal increase in those administrative tasks, that minimal "burden" does not rise to an "irreconcilable conflict" with the primary purposes of Medicaid. PhRMA certainly has failed to come forward with any evidence that as a result of such "burdens" Maine physicians will fail to conform with applicable standards of care[9] or that the State will fail to satisfy the safeguards Congress placed on prior authorization. PhMRA's facial challenge thus fails because PhRMA has not remotely demonstrated that Maine Rx cannot be implemented in a manner that will not harm Medicaid patients. *Salerno*, 481 U.S. at 745 (in a facial attack the "challenger must establish that no set of circumstances exists under which the Act would be valid.").

Finally, when seeking *certiorari*, PhRMA asserted that "no further development of the record would contribute to or alter the relevant legal analysis" of this case. Pet. at 2. Switching gears, PhRMA now proffers a "lodging" (Br. 6) containing new documents purporting to show that Medicaid patients were harmed when, independent of Maine Rx, Maine expanded its use of prior authorization in January, 2000 to make Medicaid more cost-effective.

[9] PhRMA's unsupported and cynical suggestion that Maine's physicians would rather lower their standard of care than comply with DHS prior authorization procedures is refuted by the actual experience of Dr. Richardson, a practicing Maine pediatrician who supports the use of prior authorization to "reduce the price of drugs to . . . patients who do not have drug insurance benefits and who might otherwise not be able to afford medications." J.A. 154.

PhRMA aims to prove too much: that prior authorization, in and of itself, for whatever purpose, is harmful. In any case, if all the proof of harm that PhRMA can muster is a single anecdote from a local newspaper article written in the first days of the expanded program, PhRMA's concerns should be disregarded. During the past two years Maine has collected extensive data on the success of its expanded prior authorization program, showing that a well-designed program can ensure access to all medically necessary drugs well within the time frames set by Medicaid. Accordingly, if these issues are litigated in the future in a trial court, the evidence will show that prior authorization has resulted in a variety of salutary effects, including a *decrease* in the rate of adverse drug reactions, without any evidence of harm to patients. At the very least, the resolution of a vigorously disputed factual issue such as the quality of care possible in a prior authorization program should not depend on an untested "lodging."

B. Maine Rx Advances the Goals Of Medicaid by Achieving Cost-Savings.

1. Preemption analysis focuses on whether a state statute significantly obstructs the goals of the federal statute. PhRMA's analysis, however, turns the Supremacy Clause on its head. PhRMA contends that Maine Rx must "advance" the purpose of Medicaid. Even if correct, PhRMA fails to meet even this more forgiving test because Maine Rx advances Medicaid in a number of ways.

At the most fundamental level, Maine Rx will provide medical assistance to persons of limited financial means – a Medicaid goal in itself. Pet. App. 13. Equally important,

Maine Rx will benefit Medicaid by helping control Medicaid costs, in at least three ways. First, prior authorization will have the effect of ensuring that Medicaid funds are used efficiently. Maine Rx can be expected to trigger prior authorization more often than previously. Whenever Maine Rx–induced prior authorization requirements are imposed on a particular brand-name drug for which there exist less expensive therapeutic alternatives, Medicaid will save money because the less expensive drugs will be prescribed more often. The more often prior authorization is used, the more savings Medicaid will realize.[10]

Second, as the Secretary recognizes, providing benefits to those at the gates of Medicaid eligibility will ultimately benefit Medicaid itself. Pet. App. 13-14; U.S. Br. 28-30, 49a. Maine Rx will make prescription drugs more affordable for Maine's uninsured residents, enabling them to remain healthier and more productive. The alternative is deterioration in health, leading to unemployment, disability and, ultimately, full Medicaid eligibility, with adverse fiscal impact on an already stretched Medicaid program. *Id.*

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[10] It is well within the discretion of the Commissioner to impose prior authorization only on the most expensive drugs within a therapeutic class, even for those manufacturers that do not participate in Maine Rx. See 22 Me. Rev. Stat. Ann. § 2681(13), Pet. App. 92 (Commissioner may "coordinate" his administration of Maine Rx and Medicaid "in a manner that is advantageous" to both programs and which "enhance[s] efficiency, reduce[s] the cost of prescription drugs and maximize[s] the benefits" of all of the programs he administers).

A third way in which Maine Rx facilitates Medicaid cost-savings is by allowing the State to "serve as a pharmacy benefit manager." 22 Me. Rev. Stat. Ann. § 2681, Pet. App. 86.[11] Like that of a private sector PBM, the bargaining power of DHS is a function of the number of persons enrolled in the programs it administers. Currently, the Commissioner has authority to negotiate on behalf of the nearly 150,000 persons covered by Maine Medicaid. J.A. 182. That bargaining power expands greatly, however, when the Commissioner is authorized to negotiate on behalf of both Medicaid and the estimated 325,000 persons eligible for Maine Rx. J.A. 166. This enhanced bargaining power will redound to the benefit of Medicaid because, in addition to the rebates paid uniformly across the country, Medicaid authorizes Maine to negotiate supplemental rebates to further reduce the net cost of drugs to Medicaid. 42 U.S.C. 1396r-8(a)(1). Greater bargaining power leads to larger supplemental rebates and greater cost savings for Medicaid.

2. Although generally agreeing with Maine that keeping citizens from falling into Medicaid eligibility advances the goals of the program and that prior authorization is a valid means to achieve that end (U.S. Br. at 28), the federal government still hesitates to endorse Maine Rx. Two reasons are tendered. First, the government suggests that a "demonstration project" currently in effect

[11] Judge Keeton, writing in concurrence below, also saw the benefits of the State acting as a PBM, explaining "it would be a curious irony indeed if dozens of privately organized groups of Pharmacy Benefit Managers (PBMs) could participate freely in the market for purchasing products from pharmacy product manufacturers but States as guardians and trustees for their people could not." Pet. App. 39.

may achieve the same or similar beneficial results such that Maine Rx is rendered superfluous. U.S. Br. at 22-27.[12] While both Maine Rx and the demonstration project may serve generally the same population, the demonstration project has only been approved until 2006. Further, if PhRMA wins its separate legal challenge now pending in the Court of Appeals for the District of Columbia Circuit, the demonstration project would end overnight. More fundamentally, however, the government has pointed to no authority for the proposition that a program that does not conflict with a federal statute and in fact advances its purposes is somehow preempted because another program may produce similar beneficial results.

Second, the government and Maine part company over the size of the class of uninsured citizens who can be constitutionally encompassed in this type of program.[13] In

[12] Approximately two months after the district court enjoined Maine Rx, DHS applied to the Secretary for approval of a five-year Medicaid demonstration project testing an alternative price reduction program. The Secretary approved this "Healthy Maine Prescriptions" (HMP) program pursuant to 42 U.S.C. 1315(a) (authorizing demonstration projects), and it took effect on June 1, 2001. The HMP offers price discounts to persons not eligible for Medicaid but earning no more than 300 percent of the federal poverty level. PhRMA has separately challenged HMP on the grounds that it exceeds the Secretary's approval authority under 42 U.S.C. 1315(a). The district court granted summary judgment in favor of the Secretary and the Commissioner, and PhMRA has appealed. *Pharmaceutical Research & Mfrs. of Am. v. Thompson*, 191 F. Supp.2d 48 (D.D.C. 2002), appeal pending, No. 02-5110 (D.C. Cir.). Oral argument on the appeal is scheduled for December 5, 2002.

[13] The government also suggests that Maine Rx is invalid because Maine did not ask the Secretary for approval. This concern, however, arises out of the government's substantive problem with the breadth of Maine Rx. In any event, this issue is not properly before the Court, as the Solicitor General notes. U.S. Br. 29, n.11.

the opinion of the Solicitor, Maine Rx is flawed because it might help those who are not pressed up against the gates of Medicaid eligibility. U.S. Br. at 20-21, 29. This view itself is flawed, however, because no record has been developed as to how many, if any, "not-so-needy" uninsured persons will avail themselves of Maine Rx or what possible adverse effect including these persons could have on the Medicaid program. Indeed, their inclusion, if substantial, will benefit Medicaid in light of the PBM-like role Maine Rx creates for DHS. Maine's market power increases in direct proportion to the number of persons enrolled in both Maine Rx and its Medicaid program. In other words, Maine's ability to use prior authorization to negotiate better rebate agreements for both programs is enhanced by the enrollment of even those uninsured residents who may not fit within the Solicitor General's definition of the "most" needy. By combining the Maine Rx and Medicaid populations into a single purchasing pool, DHS will obtain the bargaining power of a far larger population than either program separately provides. This will enable the Commissioner to negotiate larger Medicaid discounts than the current Medicaid discount.

III. MAINE RX DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

A. Maine Rx Does Not Violate The Dormant Commerce Clause Because Congress Has Authorized The States To Use Prior Authorization.

The Constitution provides that "The Congress shall have power ... to regulate commerce ... among the several States...." Art. I, Sec. 8, Cl. 3 (Commerce Clause). Congress' express constitutional authority implies that the

states may not regulate commerce among the states. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 87 (1987) (recognizing "dormant" aspect of the Commerce Clause). Although the dormant Commerce Clause generally prohibits states from directly regulating interstate commerce, it does not prohibit the states from doing so if authorized by Congress. *Northeast Bancorp v. Board of Governors of the Fed. Reserve Sys.*, 472 U.S. 159, 174 (1985) ("When Congress so chooses, state actions which it plainly authorizes are invulnerable to constitutional attack under the Commerce Clause").

Maine Rx does not regulate interstate commerce for the reasons set forth in the following sections. But even if that is incorrect, Maine Rx does not violate the dormant Commerce Clause because Maine is only doing what Congress has authorized it to do: impose prior authorization in Medicaid. If Maine Rx-induced prior authorization advances the purposes of Medicaid at the same time that it helps provide discounts for persons ineligible for Medicaid – and the Solicitor General and the Secretary generally agree that Congress did authorize the states to use Medicaid prior authorization as leverage to negotiate such discounts – then whatever effect Maine Rx may have on interstate commerce is an effect that Congress has approved.

B. Maine Rx Does Not Discriminate Against Interstate Commerce.

The Court of Appeals observed that "PhRMA does not contend, nor did the district court find, that the Maine Act discriminates on its face or in its effects." Pet. App. 24-25. Nonetheless, PhRMA now asserts (Br. 35-39) that Maine

Rx constitutes economic discrimination against the wholesale business of pharmaceutical manufacturers. Although this Court's economic discrimination cases have generally involved state laws that either favored in-state producers over out-of-state producers, or in-state purchasers over out-of-state purchasers, PhRMA argues that the dormant Commerce Clause should not be so limited. According to PhRMA, any law that benefits in-state interests and burdens out-of-state interests is inherently unconstitutional, regardless of its effect on commerce or economic competition.

The essential purpose of the dormant Commerce Clause is to prevent States from enacting discriminatory policies. See *CTS Corp.*, 481 U.S. at 87; *Best & Co. v. Maxwell*, 311 U.S. 454, 455 (1940); see also Donald Regan, *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 Mich. L. Rev. 1091, 1092 (1986) (dormant Commerce Clause cases "ha[ve] been concerned exclusively with preventing states from engaging in purposeful economic protectionism"). Economic discrimination is forbidden because it hinders national economic markets. See *General Motors Corp. v. Tracy*, 519 U.S. 278, 299 (1997); *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 127-28 (1978). The dormant Commerce Clause forbids the states from treating in-state economic actors more favorably than their out-of-state competitors. *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 340-41 (1989); *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579 (1986). It does not, however, forbid all actions designed to give in-state actors an advantage in the marketplace, "but only action of that description *in connection with the state's regulation of*

interstate commerce." *New Energy Co. of Indiana v. Limbach*, 486 U.S. 269, 278 (1988) (emphasis in original).

As both the district court (Pet. App. 64) and the court of appeals (Pet. App. 24-25) found, Maine Rx is not protectionist within the meaning of these well-settled dormant Commerce Clause principles. Maine Rx does not "give [in-state] producers an additional tool with which to shore up their competitive position," *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 197 (1994), and "has no impact on the relative proportions of local and out-of-state goods sold . . . ." *Exxon*, 437 U.S. at 126 n.16. It is not a "clog upon the mobility of commerce," *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 527 (1935), and it does not tip the scales of trade in favor of in-state producers. In short, Maine has not "strip[ped] away . . . the competitive and economic advantages" of out-of-state industry in favor of in-state industry. *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 351 (1987). Indeed, it is difficult to conceive of a statute that is discriminatory under the dormant Commerce Clause where, as here, there is no in-state industry to favor. See *Exxon*, 437 U.S. at 125 (there can be no finding of economic protectionism in the absence of local producers).

PhRMA suggests (Br. 35-38) that Maine Rx is impermissibly protectionist even if it does not affect economic competition, simply because it helps in-state consumers while burdening out-of-state producers. But PhRMA's apples-to-oranges comparison has no basis in *Healy*, *Brown-Forman* or *Baldwin*. In those cases the Court focused on the challenged laws' differential treatment of *economic competitors*. In each case the state law had the purpose and effect of tilting the economic playing field, benefiting in-state businesses at the expense

of their out-of-state competitors. It was the state's attempts to co-opt the competitive advantages enjoyed by out-of-state interests vis-a-vis their in-state counterparts, and the resulting distortion of the marketplace, that offended dormant Commerce Clause principles.

The approach in Maine Rx is fundamentally different from the price control schemes in *Healy*, *Brown-Forman* and *Baldwin*. Maine Rx seeks lower prices by wielding Maine's Medicaid purchasing power, not by "co-opting" the relative advantages of purchasers in other states.[14] Unlike the measures challenged in the price-control cases, Maine Rx always leaves manufacturers free to charge whatever prices they wish. Maine has only done precisely what *Brown-Forman* specifically allows: "[A] State may seek lower prices for its consumers, [so long as it does] not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." *Brown-Forman*, 476 U.S. at 580.

PhRMA's reliance on *West Lynn* is misplaced. Like the other movement-of-goods cases, the analysis in *West Lynn* focuses on the impact of the challenged state law on out-of-state economic actors *vis-a-vis their in-state competitors*. *West Lynn* invalidated a Massachusetts law that was plainly designed to shore up local industry. The revenue from a state tax on wholesale domestic and imported milk was transferred to in-state milk producers, allowing them to reduce their prices and secure a competitive advantage

[14] It is ironic that PhRMA relies exclusively on decisions that prohibited states from "leveraging" out-of-state markets, given that the entire first half of PhRMA's argument complains that Maine Rx leverages the in-state Medicaid market.

against the more efficient out-of-state farms. The Massachusetts pricing scheme offended the dormant Commerce Clause because it had the purpose and effect of improving the competitive position of Massachusetts dairy farmers and reducing the market share of out-of-state farmers.

PhRMA cites *West Lynn* for the proposition that the dormant Commerce Clause prohibits states from burdening "'any part of the stream of commerce – from wholesale to retailer to consumer.'" Pet. Br. 38 (quoting *West Lynn*, 512 U.S. at 202). From that passage PhRMA concludes that a statute that burdens out-of-state producers is unconstitutional regardless of whether it benefits in-state producers. But the entire analysis in *West Lynn* hinged on the milk pricing order's unfair "advantage to in-state *producers*." 512 U.S. at 197 n.14 (emphasis added). The Court would not have found the Massachusetts law impermissibly protectionist if the revenues had been used for the benefit of *dealers* rather than *producers*:

> If the taxes were refunded only to the dealers, there might be no impact on interstate commerce, because the dealers might not use the funds to increase the price or quantity of milk purchased from Massachusetts dairy farmers. The refund to the dealers might, therefore, result in no advantage to in-state producers. On the other hand, by refunding monies directly to the dairy farmers, the pricing order ensures that Massachusetts producers will benefit.

Id. If the state may pay a subsidy to dealers, then surely a subsidy to consumers, who are even farther down the

chain of distribution, would not infringe the dormant Commerce Clause.

West Lynn recognized that the dormant Commerce Clause is concerned with "*differential* burdens," that is, state laws that impose a greater burden on out-of-state economic actors than on their in-state competitors. 512 U.S. at 202-03 (emphasis added). PhRMA's notion (Br. 38) that any "burden" is impermissible regardless of its *differential* effect on economic competition requires a dramatic expansion of the dormant Commerce Clause and must be rejected. As one commentator has written, "not just any purpose to advantage local economic actors at the expense of foreign actors is protectionist." Regan, *supra*, at 1095. A state statute is protectionist only if "[t]he purpose [is] to advantage local actors at the expense of their foreign *competitors*." *Id.* (emphasis in original); see also *General Motors*, 519 U.S. at 300 ("In the absence of . . . competition between the supposedly favored and disfavored entities in a single market there can be no local preference . . . to which the dormant Commerce Clause may apply.").

PhRMA also contends (Br. 32-33) that Maine Rx is protectionist because it purportedly ties prices in Maine to *national* Medicaid prices. On that basis PhRMA analogizes Maine Rx to the "out-of-state price benchmark[s]" invalidated in *Brown-Forman* and *Healy*. Br. 33. But that argument also fails. Maine Rx on its face does not set the amount of manufacturer rebates, much less require rebates equal to rebates paid elsewhere. See W. Phelps, *Maine's Prescription Drug Plan: A Look into the Controversy*, 65 Alb. L. Rev. 243, 266 (2001) ("The Maine statute does not link Maine's prices to any other state"). Maine Rx rebates are negotiated, and until the injunction is lifted

any discussion of the level of the rebates and the form they might take would be wholly speculative. To be sure, the Act instructs the Commissioner to consider a variety of pricing information and then use his "best efforts" to negotiate an initial rebate equal to or greater than the Medicaid rebate. 22 Me. Rev. Stat. Ann. § 2681(4)(B). But mandating "best efforts" is a far cry from tying the rebates to out-of-state prices.[15]

Although PhRMA seems to regard the "best efforts" provision as tantamount to a mandated rebate level, the legislature recognized that the Medicaid rebate level was a target, not a requirement. The legislature understood that the Commissioner would have to enter real negotiations, and that the price reductions actually achieved by Maine Rx might be far less than those in Medicaid. That is why the Act details a system to measure the price reductions actually achieved by Maine Rx. See 22 Me. Rev. Stat. Ann. § 2693(1)(B). More significantly, if those price reductions prove inadequate, the Act imposes retail price controls directly on Maine pharmacies. *Id.* at § 2693(1)(B)(5). If, as PhRMA contends, Maine Rx rebates must equal national Medicaid rebates, there would have been no reason for the legislature to enact either the measurement provisions or the retail price controls.

Here, both the *amount* and the *form* of the rebate are left to negotiation. A manufacturer could propose a rebate

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[15] Assuming, arguendo, that Maine Rx did require rebates equal to Medicaid rebates, that still would not interfere with the commerce of any other state. Medicaid rebate amounts are uniform nationwide, and PhRMA cites no decision that has ever prohibited a state from tying prices to a national price as opposed to the price in another state.

unrelated to Medicaid rebates or any benchmark. For instance, a manufacturer could negotiate an agreement that provides a rebate of a fixed dollar amount rather than a percentage of a pricing index. Such agreements would leave the manufacturer free to adjust its Medicaid rebate amount – or any of its wholesale prices – without risk of violating Maine Rx. The Act therefore has no impact on markets or consumers in other states.

C. Maine Rx Does Not Control Commerce Beyond The State's Borders.

For non-discriminatory statutes such as Maine Rx the appropriate dormant Commerce Clause analysis requires PhRMA to show that the Act regulates the actual terms of commerce between out-of-state prescription drug manufacturers and their out-of-state wholesalers. Apparently recognizing this, PhRMA labors to show that Maine Rx "dictate[s] the terms on which buyers and sellers do business outside the state" and that it "necessarily changes the economic terms of [wholesale] transactions." Br. 27, 29.

Maine Rx simply will not do what PhRMA claims. Maine Rx only creates a system of quarterly rebate payments, the amount of which equals the product of the number of drugs of a participating manufacturer purchased by Maine Rx beneficiaries and the negotiated rebate amount for that manufacturer. As the Court of Appeals understood, this system "does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect." Pet. App. 22. The Solicitor General reached the same conclusion. U.S. Pet. Br. 17 (Maine Rx "does not regulate the terms of . . . out-of-state

transactions"). Maine Rx does not "dictate" the wholesale price, or prescribe the rule by which that price is determined. Such quarterly payments are not the actual "terms" of the transactions between manufacturers and wholesalers, and PhRMA's suggestion to the contrary is specious.

At the most fundamental level, Maine Rx has no extraterritorial application. The Maine Rx rebate is triggered only by retail sales within Maine, by Maine pharmacists, to Maine residents. Under Maine Rx, if none of a manufacturer's products is sold in Maine, the manufacturer has no obligation. The only "extraterritorial" aspect of the Maine Rx program is that it does not exempt products originating in other states from the rebate requirement. This does not turn Maine Rx into a direct regulation of drug manufacturers' wholesale transactions.[16]

This Court has never held that a state law impermissibly regulates interstate conduct merely because it has extraterritorial effects.[17] Indeed, contrary examples

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[16] PhRMA makes far too much of the fact that manufacturers sell through wholesalers, and that title to drugs passes from manufacturer to wholesaler before the drugs enter Maine. Br. 29. The goal of national economic union is not served by such formalistic considerations as the situs at which title passes. See *Exxon*, 437 U.S. at 127 (The Commerce Clause is not concerned about "the particular structure or methods of operation" of the market in question.).

[17] It is even open to question whether the "extraterritorial" branch of dormant Commerce Clause doctrine exists at all. Although some litigants have argued that the *Brown-Forman* prohibition on "directly regulat[ing]" interstate commerce would invalidate any regulation with extraterritorial effect, another panel of the First Circuit has noted that this Court has not applied *Brown-Forman* in that way. See *Grant's Dairy v. Comm'r of Maine Dep't of Agric., Food & Rural Resources*, 232 F.3d 8, 19 (1st Cir. 2000) (Selya, J.).

abound. See, *e.g.*, *CTS Corp.* 481 U.S. at 87-88 (upholding state anti-takeover law despite extraterritorial effects); *Exxon*, 437 U.S. at 125-29 (upholding state law prohibiting vertical ownership in the gasoline industry even though law had substantial impact on out-of-state companies); see also *K-S Pharmacies, Inc. v. American Home Products Corp.*, 962 F.2d 728 (7th Cir. 1992) (Easterbrook, J.) (upholding state law regulating wholesale drug prices despite extraterritorial impact). In the words of the Third Circuit, this Court "has never suggested that the dormant Commerce Clause requires Balkanization, with each state's law stopping at the border." *Instructional Sys., Inc. v. Computer Curriculum Corp.*, 35 F.3d 813, 825 (3d Cir. 1994).

PhRMA's parade of horribles (Br. 30-31) suggests that Maine and other states might "demand" rebates from out-of-state oil refiners or computer chip manufacturers on the basis of in-state sales of their products, and that "[s]uch schemes would obviously transgress the boundaries established by the Commerce Clause." *Id.* But Maine Rx provides for negotiated rebates and not "demands," and the State is hardly "regulating" commerce if the effort to collect rebates is backed only by the prospect of reduced government purchases. See *White v. Massachusetts Council of Constr. Employers, Inc.*, 460 U.S. 204 (1983) (municipal preferential purchasing policy is not a "regulation" of commerce). For example, when seeking to purchase new computers for State agencies, surely the State could favor those vendors that offer separate discounts to Maine school students. PhRMA's hypotheticals do not establish that "demanding" such concessions would hamper interstate markets, deprive economic actors in other states of

their competitive advantages, or constitute extraterritorial price regulation.

Nor can PhRMA (Br. 31-32) draw support from the interstate tax cases.[18] *Quill Corp. v. North Dakota ex rel. Heitkamp*, 504 U.S. 298 (1992) and its companions establish the test for whether the collection of taxes across state borders contravenes the dormant Commerce Clause. The inquiry focuses on the vendor's connection with the taxing state: If the vendor has no physical presence in the taxing state and only contacts customers by mail or common carrier, it lacks the requisite nexus to be taxed by that state. If, however, the vendor has even a "small sales force, plant or office" in the taxing state, 504 U.S. at 315, the tax does not infringe the Commerce Clause. Although by citing *Quill* PhRMA implies that drug manufacturers have no physical presence in Maine, that assertion is without record support. The extent of drug manufacturers' presence in Maine is a heavily fact-bound inquiry, and the sparse record on the preliminary injunction proceeding below is silent regarding such factors as the number of drug manufacturers' employees in Maine, which may be quite large.[19] PhRMA has failed to make "a clear showing that there are no in-state activities connected with sales."

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[18] PhRMA has never claimed that Maine Rx is in fact a "tax" or that the interstate tax cases are controlling. The federal district courts lack jurisdiction to enjoin state taxes. See 28 U.S.C. 1341 (Tax Injunction Act).

[19] Last year the pharmaceutical industry employed 87,892 sales representatives across the United States. See Chin, Tyler, *Drug Firms Score By Paying Doctors For Time*, Amednews.com, http://www.ama-assn.org/sci-pubs/amnews/pick_02/bil20506.htm. One must assume that many of these are in Maine.

American Oil Co. v. Neill, 380 U.S. 451 (1965), and *Quill* is therefore inapposite.

In addition, contrary to PhRMA's contention (Br. 31-32), Maine Rx would easily satisfy *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977), which held that state taxes may be applied to an activity with a substantial nexus with the taxing state. 430 U.S. at 279. The "activity" which triggers the Maine Rx rebate is retail sales activity within Maine. Although PhRMA repeatedly relies on the fiction that Maine Rx applies to wholesale transactions, only sales from Maine pharmacies trigger the rebate.

Finally, the Court should reject PhRMA's argument that Maine Rx should be invalidated because it supposedly burdens an entity without a political voice. Br. 37. Whether or not PhRMA and its member companies are formally represented in the Maine legislature, this highly organized and well-financed industry cannot seriously contend that its concerns are not heard in that body as well as Congress – the body with the constitutional authority to address both PhRMA's preemption and its Commerce Clause concerns. Moreover, numerous surrogates, including Maine doctors, patients and pharmacies, would be expected to speak out within Maine if any ill effects result from the prior authorization system that undergirds Maine Rx.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be affirmed.

Respectfully submitted,

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